

EPA Reg. No. 84542-11 – Vol. 1 Part 2

PROCESSING REQUEST

Reg # 84542-11

Decision # 498935

Description: Amended label to remove washing
directions for sub label 3 (unwashable textiles)

Material Available Electronically (see PPLS):

☒ Electronic Label/Letter Dated 1/12/15

☐ Other:

Material Sent (see jacket):

☐ Stamped Label/Letter Dated

☐ Notification Dated

☐ New CSF(s) Dated

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Julie Chao

Division: AD

Phone: 308-8735

Date: 1/12/15



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 12, 2015

Dr. Matthew Brooks, Director
Ag-Chem Consulting
12208 Quinque Lane
Clifton, VA 20124

Subject: Label Amendment – Correcting directions for Sub-Label 3 (Unwashed Textiles)
Product Name: Cupron Anti-Fungal Fibers and Fabrics III
EPA Registration Number: 84542-11
Application Date: January 6, 2015
Decision Number: 498935

Dear Dr. Brooks:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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EPA Reg. No. 84542-11
Decision No. 498935

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact me by phone at (703) 308-8735, or via email at chao.julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao", with a stylized flourish at the end.

Julie Chao, Acting Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

Master Label containing

Sublabel 1. Athlete's Foot Label

Sublabel 3: Athlete's Foot Label- no washings

Sublabel 2. Jock Itch Label

[Sublabel 1: Athlete's Foot Label]

CUPRON ANTI-FUNGAL FIBERS AND FABRICS III

[Additional Brand Name: Cupron AntiFungal Fibers]

Active Ingredient

Copper (I) Oxide

1.95 %

Other Ingredients (Garment)

98.05 %

Total

100.00 %

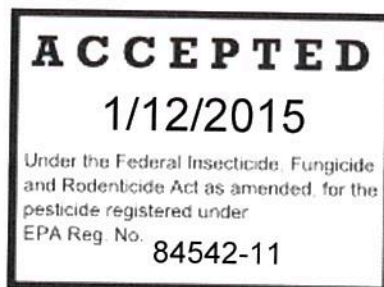
EPA Registration No. 84542- 11

EPA Establishment No *****

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by*****

Net Contents*****



Cupron Anti Fungal Fibers and Fabrics III

Master Label

1/6/2015

Page 1

Cupron Anti Fungal Fibers and Fabrics III

[When Additional Brand Name is used the statement Cupron enhanced fibers/fabric shown below is replaced with Cupron AntiFungal Fibers]

-THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Laboratory testing has shown that when cleaned regularly:

Cupron enhanced fibers/fabric will assist in reducing the spread of *T. mentagrophytes* (athlete's foot fungus).

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (athlete's foot fungus) after 12 hours of contact with [sock, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (athlete's foot fungus) on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the growth of athlete's foot fungus on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric reduce(s) the spread of *T. mentagrophytes*, athlete's foot fungus, on the surface of the sock.

Cupron enhanced fibers/fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the sock.

Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the [sock, bathmat, shoe inserts].

Cupron enhanced fibers/fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, fungus that causes athlete's foot on the sock.

THIS PRODUCT IS EFFICACIOUS UP TO 20 MACHINE WASHINGS

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

Cupron Anti Fungal Fibers and Fabrics III

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular (not compatible with silvercare machines)

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

[Cupron Anti Fungal Fibers and Fabrics III may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE SOCKS, FOOTWEAR, SHOE INSERTS AND BATHMATS.

STORAGE AND DISPOSAL

Disposal: Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

Hang Tag Label:



Cupron AntiFungal Fibers

Cupron Antifungal Fibers Kill 99.9% of *T. mentagrophytes* (athlete's foot fungus) after 12 hours of contact with [insert site]

Active Ingredient

Copper (I) Oxide	1.95%
Other Ingredients (Garment)	98.05%
Total	100%

EPA Registration No 84542-11

EPA Establishment No 3541-TN-001, 3541-AL-001

Manufactured for
Cupron Inc
Suite 123, 800 East Leigh Street, Richmond, VA 23219

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

Storage and Disposal

Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.

Master Label containing

Sublabel 1. Athlete's Foot Label

Sublabel 3: Athlete's Foot Label- no washings

Sublabel 2. Jock Itch Label

[Sublabel 2: Jock Itch Label]

CUPRON ANTI-FUNGAL FIBERS AND FABRICS III

[Additional Brand Name: Cupron AntiFungal Fibers]

Active Ingredient

Copper (I) Oxide 1.95%

Other Ingredients (Garment) 98.05%

Total: 100.00%

EPA Registration No. 84542- 11

EPA Establishment No *****

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by*****

Net Contents*****

Cupron Anti Fungal Fibers and Fabrics III

Master Label

1/6/2015

Page 5

Cupron AntiFungal Fibers and Fabrics III

-THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Laboratory testing has shown that when cleaned regularly:

- Cupron enhanced fibers / fabric will assist in reducing the spread of *T. mentagrophytes* (jock itch fungus)
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (jock itch fungus) after 12 hours of contact with the [USE SITE]
- Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on [USE SITE]
- Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of jock itch on [USE SITE]
- Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of jock itch on [USE SITE]
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (jock itch fungus) on the [USE SITE]
- Cupron enhanced fibers / fabric will inhibit the growth of *T. mentagrophytes*, jock itch fungus, on [USE SITE]
- Cupron enhanced fibers / fabric reduce(s) the spread of *T. mentagrophytes*, jock itch fungus, on the surface of the [USE SITE]
- Cupron enhanced fibers / fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, jock itch fungus, on the [USE SITE]
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, jock itch fungus, on the [USE SITE]
- Cupron enhanced fibers / fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, the fungus that causes jock itch on the [USE SITE]

THIS PRODUCT IS EFFICACIOUS UP TO 20 MACHINE WASHINGS

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular (not compatible with silvercare machines)

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

[Cupron Anti Fungal Fibers and Fabrics III may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE:-underwear, studio apparel (pants, capris, shorts, leggings, tights), yoga apparel (pants, capris, shorts, leggings, tights), run apparel (pants, capris, shorts, leggings, tights), training apparel (pants, capris, shorts, leggings, tights), team sports apparel (pants, capris, shorts, leggings, tights), team sports uniforms (pants, capris, shorts, leggings, tights), baselayer (pants, capris, shorts, leggings, tights), compression products (pants, capris, shorts, leggings, tights), warmth layers (pants, capris, shorts, leggings, tights), leg sleeves.

STORAGE AND DISPOSAL

Disposal: Discard in trash when fibers/fabric are worn out after 20 washings. Do not reuse clothing for other purposes than as sold.

Hang Tag Label:



Cupron AntiFungal Fibers

Cupron Antifungal Fibers Kill 99.9% of T. mentagrophytes (jock itch fungus) after 12 hours of contact with (insert site).

Active Ingredient

Copper (I) Oxide	1.95%
Other Ingredients (Garment)	98.05%
Total	100%

EPA Registration No 84542-11

EPA Establishment No 3541-TN-001, 3541-AL-001

Manufactured for
Cupron Inc
Suite 123, 800 East Leigh Street, Richmond, VA 23219

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

Storage and Disposal

Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.

Master Label containing

Sublabel 1. Athlete's Foot Label

Sublabel 3: Athlete's Foot Label- no washings

Sublabel 2. Jock Itch Label

[Sublabel 2: Athlete's Foot Label – no washings]

CUPRON ANTI-FUNGAL FIBERS AND FABRICS III

[Additional Brand Name: Cupron AntiFungal Fibers]

Active Ingredient

Copper (I) Oxide 1.95%

Other Ingredients (Garment) 98.05%

Total: 100.00%

EPA Registration No. 84542- 11

EPA Establishment No *****

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by*****

Net Contents*****

Cupron Anti Fungal Fibers and Fabrics III

Master Label

1/6/2015

Page 9

Cupron Anti Fungal Fibers and Fabrics III

[When Additional Brand Name is used the statement Cupron enhanced fibers/fabric shown below is replaced with Cupron AntiFungal Fibers]

-THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Cupron enhanced fibers/fabric will assist in reducing the spread of *T. mentagrophytes* (athlete's foot fungus).

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (athlete's foot fungus) after 12 hours of contact with [sock, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (athlete's foot fungus) on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the growth of athlete's foot fungus on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric reduce(s) the spread of *T. mentagrophytes*, athlete's foot fungus, on the surface of the sock.

Cupron enhanced fibers/fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the sock.

Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the [sock, bathmat, shoe inserts].

Cupron enhanced fibers/fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, fungus that causes athlete's foot on the sock.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

Cupron Anti Fungal Fibers and Fabrics III

Master Label

1/6/2015

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

Do not wash or dry clean.

[Cupron Anti Fungal Fibers and Fabrics III may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE FOOTWEAR, SHOE INSERTS.

STORAGE AND DISPOSAL

Disposal: Discard in trash when fibers/fabric are worn out. Do not reuse clothing for other purposes than as sold.

Hang Tag Label:



Cupron AntiFungal Fibers

**Cupron Antifungal Fibers Kill 99.9% of T. mentagrophytes (athlete's foot fungus) after
12 hours of contact with [insert site]**

Active Ingredient

Copper (I) Oxide	1.95%
Other Ingredients (Garment)	98.05%
Total	100%

EPA Registration No 84542-11

EPA Establishment No 3541-TN-001, 3541-AL-001

Manufactured for
Cupron Inc
Suite 123, 800 East Leigh Street, Richmond, VA 23219

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not wash.
Do not dry clean.

Storage and Disposal

Discard in trash when worn out. Do not reuse for
Other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.



AG-CHEM CONSULTING

PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS@AG-CHEM.COM
(703) 266-4377 FAX

January 6, 2015

Julie Chao
Product Manager 34
Insecticide Branch
Antimicrobials Division (7510P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

**Subject: Cupron AntiFungal Fibers and Fabrics III
Revisions to correct inconsistencies in hangtag for sublabel 3
EPA Reg. No. 84542-11**

Dear Ms. Chao,

Ag-Chem Consulting, on behalf of Cupron, Inc., hereby submits the following amendment to correct a typographical error in sublabel 3. Although this is for unwashed textiles, the hang tag inadvertently contained washing language which is inconsistent with the master sublabel language. This amendment corrects that error.

Should you have any questions or require additional information, please do not hesitate to contact me at 703-266-0128.

Very Sincerely,

Dr. Matthew Brooks
Director, Ag-Chem Consulting
An Authorized Representative for Cupron Inc



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Cupron Inc./84542-11	2. EPA Product Manager Chao	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Cupron Inc. /Cupron Anti-Fungal Fibers and Fabrics III	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Cupron Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to revise hangtag on sublabel to delete washing instructions for when product is part of nonwashable items for athlete's foot claims

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) _____	None
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2 lb.		5. Location of Label Directions <input checked="" type="checkbox"/> on packaging	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper, glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Dr. Matthew Brooks		Title Regulatory Consultant	
		Telephone No. (Include Area Code) 703-266-0128	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant	
4. Typed Name Dr. Matthew Brooks		5. Date January 6, 2015	

PROCESSING REQUEST

Reg # 84542-11

Decision # 498707

Description: Amended label

Material Available Electronically (see PPLS):

☒ Electronic Label/Letter Dated 8/1/2/15

☐ Other:

Material Sent (see jacket):

☐ Stamped Label/Letter Dated

☐ Notification Dated

☐ New CSF(s) Dated

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Julie Chao

Division: AB/RMB2

Phone: 308-8735

Date: 1/2/15



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 2, 2015

Dr. Matthew Brooks, Director
Ag-Chem Consulting
12208 Quinque Lane
Clifton, VA 20124

Subject:

Label Amendment – Additional Sub-Label for Non-Washable Materials
Product Name: Cupron Anti-Fungal Fibers and Fabrics III
EPA Registration Number: 84542-11
Application Date: August 19, 2014
Decision Number: 498707

Dear Dr. Brooks:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2
EPA Reg. No. 84542-11
Decision No. 498707

with FIFRA section 6. If you have any questions, please contact me by phone at (703) 308-8735, or via email at chao.julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao", with a stylized flourish at the end.

Julie Chao, Acting Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

Master Label containing

Sublabel 1. Athlete's Foot Label

Sublabel 3: Athlete's Foot Label- no washings

Sublabel 2. Jock Itch Label

[Sublabel 1: Athlete's Foot Label]

CUPRON ANTI-FUNGAL FIBERS AND FABRICS III

[Additional Brand Name: Cupron AntiFungal Fibers]

Active Ingredient

Copper (I) Oxide 1.95 %

Other Ingredients (Garment) 98.05 %

Total 100.00 %

EPA Registration No. 84542- 11

EPA Establishment No *****

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by*****

Net Contents*****

ACCEPTED

1/2/2015

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under

EPA Reg No. **84542-11**

Cupron Anti Fungal Fibers and Fabrics III

Master Label

8/19/2014

Page 1

Cupron Anti Fungal Fibers and Fabrics III

[When Additional Brand Name is used the statement Cupron enhanced fibers/fabric shown below is replaced with Cupron AntiFungal Fibers]

-THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Laboratory testing has shown that when cleaned regularly:

Cupron enhanced fibers/fabric will assist in reducing the spread of *T. mentagrophytes* (athlete's foot fungus).

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (athlete's foot fungus) after 12 hours of contact with [sock, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (athlete's foot fungus) on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the growth of athlete's foot fungus on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric reduce(s) the spread of *T. mentagrophytes*, athlete's foot fungus, on the surface of the sock.

Cupron enhanced fibers/fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the sock.

Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the [sock, bathmat, shoe inserts].

Cupron enhanced fibers/fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, fungus that causes athlete's foot on the sock.

THIS PRODUCT IS EFFICACIOUS UP TO 20 MACHINE WASHINGS

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

Cupron Anti Fungal Fibers and Fabrics III

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular (not compatible with silvercare machines)

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

[Cupron Anti Fungal Fibers and Fabrics III may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE SOCKS, FOOTWEAR, SHOE INSERTS AND BATHMATS.

STORAGE AND DISPOSAL

Disposal: Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

Hang Tag Label:



Cupron AntiFungal Fibers

Cupron Antifungal Fibers Kill 99.9% of T. mentagrophytes (athlete's foot fungus) after 12 hours of contact with socks.

Active Ingredient

Copper (I) Oxide	1.95%
Other Ingredients (Garment)	98.05%
Total	100%

EPA Registration No 84542-11

EPA Establishment No 3541-TN-001, 3541-AL-001

Manufactured for
Cupron Inc
Suite 123, 800 East Leigh Street, Richmond, VA 23219

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

Storage and Disposal

Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.

Master Label containing

Sublabel 1. Athlete's Foot Label

Sublabel 3: Athlete's Foot Label- no washings

Sublabel 2. Jock Itch Label

[Sublabel 2: Jock Itch Label]

CUPRON ANTI-FUNGAL FIBERS AND FABRICS III

[Additional Brand Name: Cupron AntiFungal Fibers]

Active Ingredient

Copper (I) Oxide 1.95%

Other Ingredients (Garment) 98.05%

Total: 100.00%

EPA Registration No. 84542- 11

EPA Establishment No *****

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by*****

Net Contents*****

Cupron Anti Fungal Fibers and Fabrics III

Master Label

8/19/2014

Page 5

Cupron AntiFungal Fibers and Fabrics III

-THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Laboratory testing has shown that when cleaned regularly:

- Cupron enhanced fibers / fabric will assist in reducing the spread of *T. mentagrophytes* (jock itch fungus)
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (jock itch fungus) after 12 hours of contact with the [USE SITE]
- Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on [USE SITE]
- Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of jock itch on [USE SITE]
- Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of jock itch on [USE SITE]
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (jock itch fungus) on the [USE SITE]
- Cupron enhanced fibers / fabric will inhibit the growth of *T. mentagrophytes*, jock itch fungus, on [USE SITE]
- Cupron enhanced fibers / fabric reduce(s) the spread of *T. mentagrophytes*, jock itch fungus, on the surface of the [USE SITE]
- Cupron enhanced fibers / fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, jock itch fungus, on the [USE SITE]
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, jock itch fungus, on the [USE SITE]
- Cupron enhanced fibers / fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, the fungus that causes jock itch on the [USE SITE]

THIS PRODUCT IS EFFICACIOUS UP TO 20 MACHINE WASHINGS

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular (not compatible with silvercare machines)

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

[Cupron Anti Fungal Fibers and Fabrics III may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE:-underwear, studio apparel (pants, capris, shorts, leggings, tights), yoga apparel (pants, capris, shorts, leggings, tights), run apparel (pants, capris, shorts, leggings, tights), training apparel (pants, capris, shorts, leggings, tights), team sports apparel (pants, capris, shorts, leggings, tights), team sports uniforms (pants, capris, shorts, leggings, tights), baselayer (pants, capris, shorts, leggings, tights), compression products (pants, capris, shorts, leggings, tights), warmth layers (pants, capris, shorts, leggings, tights), leg sleeves.

STORAGE AND DISPOSAL

Disposal: Discard in trash when fibers/fabric are worn out after 20 washings. Do not reuse clothing for other purposes than as sold.

Hang Tag Label:



Cupron AntiFungal Fibers

Cupron Antifungal Fibers Kill 99.9% of T. mentagrophytes (jock itch fungus) after 12 hours of contact with (insert site).

Active Ingredient

Copper (I) Oxide	1.95%
Other Ingredients (Garment)	98.05%
Total	100%

EPA Registration No 84542-11

EPA Establishment No 3541-TN-001, 3541-AL-001

Manufactured for
Cupron Inc
Suite 123, 800 East Leigh Street, Richmond, VA 23219

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

Storage and Disposal

Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.

Master Label containing

Sublabel 1. Athlete's Foot Label

Sublabel 3: Athlete's Foot Label- no washings

Sublabel 2. Jock Itch Label

[Sublabel 3: Athlete's Foot Label- no washings]

CUPRON ANTI-FUNGAL FIBERS AND FABRICS III

[Additional Brand Name: Cupron AntiFungal Fibers]

Active Ingredient

Copper (I) Oxide 1.95 %

Other Ingredients (Garment) 98.05 %

Total 100.00 %

EPA Registration No. 84542- 11

EPA Establishment No *****

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by*****

Net Contents*****

Cupron Anti Fungal Fibers and Fabrics III

Master Label

8/19/2014

Page 9

Cupron Anti Fungal Fibers and Fabrics III

[When Additional Brand Name is used the statement Cupron enhanced fibers/fabric shown below is replaced with Cupron AntiFungal Fibers]

-THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Cupron enhanced fibers/fabric will assist in reducing the spread of *T. mentagrophytes* (athlete's foot fungus).

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (athlete's foot fungus) after 12 hours of contact with [sock, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (athlete's foot fungus) on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the growth of athlete's foot fungus on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric reduce(s) the spread of *T. mentagrophytes*, athlete's foot fungus, on the surface of the sock.

Cupron enhanced fibers/fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the sock.

Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the [sock, bathmat, shoe inserts].

Cupron enhanced fibers/fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, fungus that causes athlete's foot on the sock.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

Do not wash or dry clean.

[Cupron Anti Fungal Fibers and Fabrics III may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE FOOTWEAR AND SHOE INSERTS.

STORAGE AND DISPOSAL

Disposal: Discard in trash when fibers/fabric are worn out. Do not reuse clothing for other purposes than as sold.

Hang Tag Label:



Cupron AntiFungal Fibers

Cupron Antifungal Fibers Kill 99.9% of T. mentagrophytes (athlete's foot fungus) after 12 hours of contact with socks.

Active Ingredient

Copper (I) Oxide	1.95%
Other Ingredients (Garment)	98.05%
Total	100%

EPA Registration No 84542-11

EPA Establishment No 3541-TN-001, 3541-AL-001

Manufactured for
Cupron Inc
Suite 123, 800 East Leigh Street, Richmond, VA 23219

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

Storage and Disposal

Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.



AG-CHEM CONSULTING

PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS@AG-CHEM.COM
(703) 266-4377 FAX

August 19, 2014

Jacqueline Hardy
Product Manager 34
Insecticide Branch
Antimicrobials Division (7510P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

**Subject: Cupron AntiFungal Fibers and Fabrics III
Amendment to add additional sublabel
EPA Reg. No. 84542-11**

Dear Ms. Hardy,

Ag-Chem Consulting, on behalf of Cupron, Inc., hereby submits the following amendment to an additional sublabel to the above product. This sublabel deletes the washing instructions for the previous athlete's foot use sublabel. This is for when the fibers are incorporated into nonwashable products. Having washing instructions on products which can't be laundered is confusing for consumers. No other changes have been included in the new sublabel.

Should you have any questions or require additional information, please do not hesitate to contact me at 703-266-0128.

Very Sincerely,

Dr. Matthew Brooks
Director, Ag-Chem Consulting
An Authorized Representative for Cupron Inc



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Cupron Inc./84542-11	2. EPA Product Manager Hardy	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Cupron Inc. /Cupron Anti-Fungal Fibers and Fabrics III	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Cupron Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to add additional sublabel to delete washing instructions for when product is part of nonwashable items for athlete's foot claims

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) _____	None
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2 lb.		5. Location of Label Directions <input checked="" type="checkbox"/> on packaging	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Dr. Matthew Brooks		Title Regulatory Consultant	Telephone No. (Include Area Code) 703-266-0128
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant	
4. Typed Name Dr. Matthew Brooks		5. Date August 19, 2014	

Material Sent for Data Extraction

REG # 84542-11

Description: Amendment

Material (s) Sent to Data Extraction Contractors

- ☐ New Stamped label Dated:
- ☐ Notification Dated:
- ☐ New CSF(s) Dated:
- ☒ Other: Accepted data for MRIDs 49486100 & 01

Decision #:

423664

Other Action/Comments:

Reviewer: Lorena Rivas

Phone: 703-305-5027

Division: AD

Date: December 16, 2014

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

December 11, 2014

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Dr. Matthew Brooks, Ph.D.
Cupron Technologies
c/o Ag-Chem Consulting
12208 Qunique Lane
Clifton, VA 20124

Subject: Storage Stability and Corrosion Characteristics Data
Product Name: Cupron Anti-Fungal Fibers and Fabrics III
EPA Reg. No. 84542-11
EPA Decision No. 496875

Dear Dr. Brooks:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3 (c) 7 A as amended, is acceptable.

Proposed Amendment:

- Minor formulation change, accelerating the aging of 75% Cupron Polyester/25% Nylon, for EPA Reg. 84542-11: Accelerated Storage Stability and Corrosion Characteristics study.

Data Summary

Data Requirement	Means of Support	Status
The OPPTS Guideline Series 830.6317 830.6320	Submitted study, MRID's 49486100 and 49486101	Acceptable.

General Comments

The study submitted to fulfill the conditional data requirement referred to above, in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable. A copy of the review is enclosed. The condition of registration is considered fulfilled. Should you have any questions, please contact me at 703-308-8735 or chao.julie@epa.gov.

Sincerely,

A handwritten signature in blue ink, consisting of several fluid, overlapping strokes that form a stylized representation of the name Julie Chao.

for

Julie Chao, Acting Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

December 5, 2014

DP BARCODE: 423664
MRID : 49486100 and 49486101
SUBJECT: Cupron Anti-Fungal Fibers and Fabrics III
REG. NO. 84542-11
DOCUMENT TYPE: Product Chemistry Review
Manufacturing-use [] OR End-use Product [X]

INGREDIENTS:

<u>PC Code(s)</u>	<u>CAS Number</u>	<u>Active Ingredient(s)</u>
025601	1317-39-1	Cuprous oxide

TEST LAB: N/A
SUBMITTER: Ag-Chem Consulting
GUIDELINE: Product Chemistry
ORGANIZATION: AD\PSB\CTT
REVIEWER: Lynette T. Umez-Eronini
APPROVED BY: Karen P. Hicks
APPROVED DATE: December 5, 2014
COMMENT: This for non-food use.

L. T. Umez-Eronini
12/8/2014

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Office of Pesticide Programs

Antimicrobials Division (AD)

December 5, 2014

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 84542-11
Product Name: Cupron Anti-Fungal Fibers and Fabrics III
DP Barcode: 423664

CODE: (570) Conditional Registration Follow-Up; Data Required;

DATE DUE: February 1, 2015

FROM: Lynette T. Umez-Eronini, Chemist *Lynette T. Umez-Eronini*
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Chris Jiang
for KPH

TO: Julie Chao PM#34/Lorena Rivas
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Cupron Technologies

PRODUCT FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Copper (I) oxide (6%)	1.95
<u>Other Ingredients (Garment):</u>	<u>98.05</u>
Total:	100

84542-11_D423664_Cupron Anti-Fungal Fibers and Fabrics III

BACKGROUND:

The consultant, Ag-Chem Consulting, on behalf of Cupron Technologies has submitted data requirements for OPPTS 830.6317 and 830.6320 guidelines for a non-integrated end-use product called Cupron Anti-Fungal Fibers and Fabrics III. The product is a fabric for reducing the fungus that is the causative agent of athlete's foot on socks, bathmats and shoe inserts. This product is for food use.

The original data package included:

1. A letter from the applicant's representative to EPA, October 13, 2014.
2. EPA Form 8570-1 (Amendment), October 1, 2014.
3. Product label, dated May 15, 2014.
- 4.

49486100	Cupron, Inc. (2014) Submission of Product Chemistry Data in Support of the Registration of Cupron Anti-Fungal Fiber and Fabrics III. Transmittal of 1 Study.
49486101	Gravelle, W. (2014) 75% Cupron Polyester / 25% Nylon: Accelerated Storage Stability and Corrosion Characteristics. Project Number: 38358, P802, 140227/4D. Unpublished study prepared by Product Safety Laboratories. 18p.

FINDINGS:

1. The basic Confidential Statement of Formula, January 30, 2013 is used as a reference.
2. An accelerated storage stability along with corrosion characteristic study was done for 60 days from 49.2-53.7°C.
3. The test substance which comprises of the product (EPA Registration No. 84542-11) was placed in a container (Ziploc plastic bag) in a 50°C oven for 60 days after the initial determination of the active ingredient.
4. The container was weighed prior to storage.
5. After the storage period, a slight weight change in the container was observed.
6. During the storage period, the container was evaluated for effects of corrosion. No sign of cracking in the container were observed.
7. The result of the storage stability study is shown in the following table:

Test Substance Identification	Initial	Day 60
	Copper (I) Oxide Concentration %	
75% Cupron Polyester/25% Nylon, EPA Registration #84542-11; Lot #: 501	2.00	1.95

- | | | | |
|----|--------------------------------|------------------------|---------------------------------------|
| 8. | <u>Active</u>
Cuprous oxide | <u>Nominal</u>
1.95 | <u>Certified Limit</u>
1.85 – 2.05 |
|----|--------------------------------|------------------------|---------------------------------------|
- The concentration of active ingredient after the 60 day period falls within EPA Standard Certified Limits.
9. The test substance was found to show no signs of discoloration and no change in the physical appearance was observed.
 10. A statement of Good Laboratory Practice (GLP) compliance was provided for the study assigned MRID 49486101. The study was conducted in compliance with the GLP standards as set forth in 40 Part 160.
 11. OPPTS 830.6317 Storage Stability and 830.6320 Corrosion Characteristics chemistry data requirements applicable to end-use products have been met (see MRID 49486101)

CONCLUSION:

The results of the 60 day accelerated storage stability and corrosion characteristics studies show that the concentration of active ingredient is maintained within the range of the certified limits for the active in the product. Neither the product nor its container showed any significant signs of deterioration. The study (MRID 49486101) provided is found to be acceptable. OPPTS 830.6317 Storage Stability and 830.6320 Corrosion Characteristics chemistry data requirements applicable to end-use products have been met (see MRID 49486101).

DATA PACKAGE BEAN SHEET

Date: 04-Nov-2014

Page 1 of 2

Decision #: 496875

DP #: (423664)

NON PRIA

Parent DP #:

Submission #: 959042

E-Sub #:

*** Registration Information ***

Registration: 84542-11 - CUPRON ANTI-FUNGAL FIBERS AND FABRICS III

Company: 84542 - CUPRON INC.

Risk Manager: RM 34 - Sharon Carlisle - (703) 308-6427 Room# PY1 S-8913

Risk Manager Reviewer: Lorena Rivas LRIVAS

Sent Date: 14-Oct-2014

PRIA Due Date: 01-Feb-2015

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (570) CONDITIONAL REGISTRATION FOLLOW-UP; DATA REQUIRED; REQUIRES RD REVIEW

Ingredients: 025601, Cuprous oxide(1.95%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 04-Nov-2014

Due Back:

DP Ingredient: 025601, Cuprous oxide

DP Title: Product Chemistry

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Organization: AD / PSB

Team Name: CTT

Reviewer Name:

Contractor Name:

Date In

Date Out

11/5
11/6
11/7

Last Possible Science Due Date: 23-Nov-2014

Science Due Date:

Sub Data Package Due Date:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Please review the Storage Stability & Corrosion Characteristics Study regarding the accelerating the aging of 75% Cupron Polyester/ 25% Nylon, for EPA Reg. 84542-11 by heating MRID # 49486101.

Acceptability

Please review the study for acceptability. Picked up 11/7/2014



Ag-Chem Consulting
Pesticide Science and Registration
12208 Quinque Lane, Clifton VA 20124
(703) 266-0128 mwbrooks01@yahoo.com
(703) 266-4377 Fax

49486100

October 13, 2014

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington VA 22202

Attn: Julie Chao PM 34
Antimicrobial Division (AD)

**Re: Fulfilling a Condition of Registration of Cupron Anti-fungal Fiber and
Fabrics III,
EPA File Symbol 84542-11**

Dear Ms. Chao,

On behalf of Cupron Inc., Ag-Chem Consulting LLC is hereby submitting the following data, formatted in accordance with Pesticide Registration notice 2011-3, in fulfilling a condition of registration.

Guideline	MRID	Study Title
OPPTS 830.6317 830.6320	49486101	75% Cupron Polyester / 25% Nylon, EPA Registration #84542-11: Accelerated storage Stability and Corrosion Characteristics Study # 38358

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of Cupron Inc.



Receipt for Section 3



S: 959042

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☐ No

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Billable: ☐ Yes ☒ No

Company: 84542 CUPRON INC.

V

Print Letter

Enter More Information

Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 84542-11

Product Name: CUPRON ANTI-FUNGAL FIBERS AND FABRICS

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 13-Oct-2014



OPP Rec'd Date: 14-Oct-2014



Front End Date: 14-Oct-2014



Risk Manager Send Date: 14-Oct-2014



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Storage stability and corrosion characteristics study

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Des

Study

View/Edit

90-1045

Memorandum

Date: 10 / 21 / 14

To: PM 34, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission

A-570
496875



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 21, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AG-CHEM CONSULTING
CUPRON INC.
12208 QUINQUE LANE
CLIFTON, VA 20124

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 14-OCT-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Material Sent for Data Extraction

Reg # 84542-11

Description: 302

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated 5/15/14

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: _____

☐ Decision #: 488341

☐ Other Action/Comments: _____

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Stacey GRIGSBY

Phone: 305.6440 Division: AD

Date: 5/15/14



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 15 2014

Dr. Matthew Brooks
Cupron Technologies
c/o Ag-Chem Consulting
12208 Qunique Lane
Clifton, VA 20124

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: **Cupron Anti-Fungal Fibers and Fabrics III**
EPA Registration Number: 84542-11
Application Date: February 19, 2014
Receipt Date: February 20, 2014

Dear Dr. Brooks:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide (FIFRA), as amended, is unacceptable.

Proposed Amendment

- Split current label into two sublabels and adding Jock itch Claim

Label Deficiencies

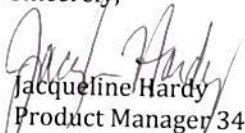
A stamped label is enclosed for your records. This labeling supersedes all previous labeling. The next printing of this product must use this labeling unless subsequent changes have been approved. You must submit one copy of the final printed label before selling or distributing the product bearing the revised labeling. In accordance with 40 CFR 152.130©, you must distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling, or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and it's implementing regulations at 40 CFR 152.3.

General Comments

If you would like to add these uses to the product label, please submit appropriate efficacy data to support these claims.

If you have further questions concerning this letter, then please contact me by telephone at (703) 308-6416 or by e-mail at hardy.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 308-6440 or by email at grigsby.stacey@epa.gov. When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

Sincerely,


Jacqueline Hardy
Product Manager 34

Regulatory Management Branch II
Antimicrobials Division (7510P)

Master Label containing

Sublabel 1. Athlete's Foot Label

Sublabel 2. Jock Itch Label

[Sublabel 1: Athlete's Foot Label]

CUPRON ANTI-FUNGAL FIBERS AND FABRICS II

[Additional Brand Name: Cupron AntiFungal Pro Fibers]

Active Ingredient	
Copper (I) oxide	2.6 %
Other Ingredients (Garment)	97.4 %
Total	100.0 %

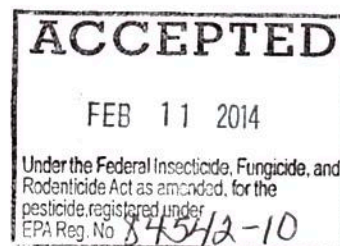
EPA Registration No. 84542- 10

EPA Establishment No *****

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by*****

Net Contents*****



Cupron Anti Fungal Fibers and Fabrics II

Master Label

8/27/2013

Page 1

Cupron Anti Fungal Fibers and Fabrics II

[When Additional Brand Name is used the statement Cupron enhanced fibers/fabric shown below is replaced with Cupron AntiFungal Pro Fibers]

-THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Laboratory testing has shown that when cleaned regularly:

Cupron enhanced fibers/fabric will assist in reducing the spread of *T. mentagrophytes* (athlete's foot fungus).

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (athlete's foot fungus) after 12 hours of contact with [sock, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (athlete's foot fungus) on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the growth of athlete's foot fungus on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric reduce(s) the spread of *T. mentagrophytes*, athlete's foot fungus, on the surface of the sock.

Cupron enhanced fibers/fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the sock.

Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the [sock, bathmat, shoe inserts].

Cupron enhanced fibers/fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, fungus that causes athlete's foot on the sock.

THIS PRODUCT IS EFFICACIOUS UP TO 20 MACHINE WASHINGS

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

Cupron Anti Fungal Fibers and Fabrics II

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular (not compatible with silvercare machines)

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

[Cupron Anti Fungal Fibers and Fabrics II may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE SOCKS, FOOTWEAR, SHOE INSERTS AND BATHMATS.

STORAGE AND DISPOSAL

Disposal: Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

Hang Tag Label:



ABN: Cupron AntiFungal Pro Fibers

Cupron Antifungal Pro Fibers Kill 99.9% of T. mentagrophytes (athlete's foot fungus) after 12 hours of contact with socks.

Active Ingredient

Copper (I) Oxide	2.6%
Other Ingredients (Garment)	97.4%
Total	100%

EPA Registration No 84542-10

EPA Establishment No 3541-TN-001, 3541-AL-001

Manufactured for
Cupron Inc
Suite 123, 800 East Leigh Street, Richmond, VA 23219

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

Storage and Disposal

Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.

Master Label containing

Sublabel 1. Athlete's Foot Label

Sublabel 2. Jock Itch Label

[Sublabel 2: Jock Itch Label]

CUPRON ANTI-FUNGAL FIBERS AND FABRICS II

[Additional Brand Name: Cupron AntiFungal Pro Fibers]

Active Ingredient

Copper (I) oxide 2.6%

Other Ingredients (Garment) 97.4%

Total: 100.00%

EPA Registration No. 84542- 10

EPA Establishment No *****

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by*****

Net Contents*****

Cupron Anti Fungal Fibers and Fabrics II

Master Label

8/27/2013

Page 5

Cupron AntiFungal Fibers and Fabrics II

-THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Laboratory testing has shown that when cleaned regularly:

- Cupron enhanced fibers / fabric will assist in reducing the spread of *T. mentagrophytes* (jock itch fungus)
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (jock itch fungus) after 12 hours of contact with the [USE SITE]
- Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on [USE SITE]
- Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of jock itch on [USE SITE]
- Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of jock itch on [USE SITE]
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (jock itch fungus) on the [USE SITE]
- Cupron enhanced fibers / fabric will inhibit the growth of *T. mentagrophytes*, jock itch fungus, on [USE SITE]
- Cupron enhanced fibers / fabric reduce(s) the spread of *T. mentagrophytes*, jock itch fungus, on the surface of the [USE SITE]
- Cupron enhanced fibers / fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, jock itch fungus, on the [USE SITE]
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, jock itch fungus, on the [USE SITE]
- Cupron enhanced fibers / fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, the fungus that causes jock itch on the [USE SITE]

THIS PRODUCT IS EFFICACIOUS UP TO 20 MACHINE WASHINGS

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular (not compatible with silvercare machines)

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

[Cupron Anti Fungal Fibers and Fabrics may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE:-underwear, studio apparel (pants, capris, shorts, leggings, tights), yoga apparel (pants, capris, shorts, leggings, tights), run apparel (pants, capris, shorts, leggings, tights), training apparel (pants, capris, shorts, leggings, tights), team sports apparel (pants, capris, shorts, leggings, tights), team sports uniforms (pants, capris, shorts, leggings, tights), baselayer (pants, capris, shorts, leggings, tights), compression products (pants, capris, shorts, leggings, tights), warmth layers (pants, capris, shorts, leggings, tights), leg sleeves.

STORAGE AND DISPOSAL

Disposal: Discard in trash when fibers/fabric are worn out after 20 washings. Do not reuse clothing for other purposes than as sold.

Hang Tag Label:



ABN: Cupron AntiFungal Pro Fibers

Cupron Antifungal Pro Fibers Kill 99.9% of T. mentagrophytes (jock itch fungus) after 12 hours of contact with (INSERT USE SITE).

Active Ingredient

Copper (I) Oxide	2.6%
Other Ingredients (Garment)	97.4%
Total	100%

EPA Registration No 84542-10

EPA Establishment No

Manufactured for

Cupron Inc

Suite 123, 800 East Leigh Street, Richmond, VA 23219

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

Storage and Disposal

Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.

Cupron Anti Fungal Fibers and Fabrics II

Master Label

8/27/2013

Page 8



AG-CHEM CONSULTING

PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE. CLIFTON VA 20124
(703) 266-0128 MWBROOKS@AG-CHEM.COM
(703) 266-4377 FAX

August 28, 2013

Jacqueline Campbell
Product Manager 34
Insecticide Branch
Antimicrobials Division (7510P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Cupron AntiFungal Fibers and Fabrics II
Amendment to split current label into two sublabels and add Jock
Itch claims
EPA Reg. No. 84542-10

Dear Ms. Campbell,

Ag-Chem Consulting, on behalf of Cupron, Inc., hereby submits the following amendment to split the current label of the above product into two sublabels, one to treat Athlete's Foot and one to treat Jock Itch. We have also revised the hang tag label to accurately reflect the commercial hang tag.

Should you have any questions or require additional information, please do not hesitate to contact me at 703-266-0128.

Very Sincerely,

Dr. Matthew Brooks
Director, Ag-Chem Consulting
An Authorized Representative for Cupron Inc



Shipment Receipt

Address Information

Ship to:	Ship from:
Document Processing	Matt Brooks
Office of Pesticide Programs-	Ag-Chem Consulting
EPA	
2777 CRYSTAL DR	12208 Quinque Lane
ROOM S-4900, ONE	
POTOMAC YARD	
ARLINGTON, VA	Clifton, VA
222023553	20124
US	US
7033055263	7032660128

Shipment Information:

Tracking no.: 796564217207
 Ship date: 08/28/2013
 Estimated shipping charges: 18.04

Package Information

Service type: Priority Overnight
 Package type: FedEx Envelope
 Number of packages: 1
 Total weight: 0.50 LBS
 Declared Value: 0.00 USD
 Special Services:
 Pickup/Drop-off: Use an already scheduled pickup at my location

Billing Information:

Bill transportation to: MyAccount-542
 Your reference: Aberco
 P.O. no.:
 Invoice no.:
 Department no.:

Thank you for shipping online with FedEx ShipManager at fedex.com.

Please Note

FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500 (e.g., jewelry, precious metals, negotiable instruments and other items listed in our Service Guide). Written claims must be filed within strict time limits. Consult the applicable FedEx Service Guide for details. The estimated shipping charge may be different than the actual charges for your shipment. Differences may occur based on actual weight, dimensions, and other factors. Consult the applicable [FedEx Service Guide](#) or the FedEx Rate Sheets for details on how shipping charges are calculated.



United States
Environmental Protection Agency
Washington, DC 20460

Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number

Cupron Inc /84542-10

2. EPA Product Manager

Campbell

3. Proposed Classification

☒ None ☐ Restricted

4. Company/Product (Name)

Cupron Inc /Cupron Anti-Fungal Fibers and Fabrics II

PM#

34

5. Name and Address of Applicant (Include ZIP Code)

Cupron Inc
c/o Ag-Chem Consulting
12208 Quinque Lane Clifton Va 20124

6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

☐ Check if this is a new address

Product Name _____

Section - II

☒ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated _____

Notification Explain below

☐ Final printed labels in response to Agency letter dated _____
"Me Too" Application.

☒ Other - Explain below.

Explanation Use additional page(s) if necessary. (For section I and Section II.)

Amendment to split current label into two sublabels and add Jock Itch claim

Section - III

1. Material This Product Will Be Packaged In.

Child-Resistant Packaging

☐ Yes
☒ No

Unit Packaging

☐ Yes
☒ No

Water Soluble Packaging

☐ Yes
☒ No

2. Type of Container

☐ Metal
☐ Plastic
☐ Glass
☐ Paper
☒ Other (Specify) _____ None

* Certification must be submitted

If "Yes" Unit Packaging wgt. _____

No. per container _____

If "Yes" Package wgt _____

No. per container _____

3. Location of Net Contents Information

☒ Label ☐ Container

4. Size(s) Retail Container

2 lb.

5. Location of Label Directions

☒ On garment hangtag

6. Manner in Which Label is Affixed to Product

☐ Lithograph
☐ Paper glued
☐ Stenciled

☒ Other affixed with plastic cord

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name

Dr. Matthew Brooks

Title

Regulatory Consultant

Telephone No. (Include Area Code)

703-266-0128

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received

(Stamped)

2. Signature

3. Title

Regulatory Consultant

4. Typed Name

Dr. Matthew Brooks

5. Date

August 28, 2013

Material Sent for Data Extraction

Reg # 84542-11

Description: 332

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☐ Notification Dated 6/18/4

☐ New CSF(s) Dated _____

☐ Other: _____

☐ Decision #: 491439

☐ Other Action/Comments: _____

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Stacey GRIGSBY

Phone: 305. 6440 Division: AD

Date: 6/18/14



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 18 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Matthew Brooks
Cupron Inc.
c/o Ag-Chem Consulting
12208 Quinque Lane
Clifton, VA 20124

Subject: **CUPRON ANTI-FUNGAL FIBERS AND FABRICS**
EPA Registration No.: 84542-11
Application Date: May 19, 2014
Receipt Date: May 20, 2014

Dear Dr. Brooks:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c) 9.

Proposed Notification:

- Add Additional Alternative Confidential Statement of Formula (CSF)

General Comment:

Based on a review of the material submitted, your notification to update as referenced above is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at hardy.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by e-mail at grigsby.stacey@epa.gov during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacqueline Hardy", is written over the typed name.

Jacqueline Hardy
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branches

ORIGINATOR/PRODUCT REVIEWER: Stacey Grigsby						RMB II TEAM ____34____	
Decision No: 491439			Submission No: 952530			EPA File Symbol/Reg No. 84542-11	
PRIA Fee: \$ _____			Action Code: 332				
GPRA:	FQPA		Non-FQPA			Product Re-reg.	
PRIA:	ME-TOO	New Use <input type="checkbox"/>		Old Chemical		New Chemical <input type="checkbox"/>	Amend w/data
		MONTH	DAY		YEAR		
APPLICATION DATE		5	19		2014		
EPA PIN DATE		5	20		2014		
DATE PM RECEIVED FROM FRONT END					2014		
DATE SENT TO SCIENCE					2014		
DATE RECEIVED FROM SCIENCE							
NEGOTIATED DUE DATE					DATE DUE OUT OF AGENCY		6/19/14
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure/R residue
<p>Comments: Please provide hard and electronic copy of deliverable(s).</p> <p>Notification: Please review the alternate CSF. Registrant is adding new source of ai</p>							

Receipt for Section 3

S: 952530

Milestone: _mail:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Notification

Fee For Service: ☐ Yes ☒ No

Company: 84542 CUPRON INC.

V

Print Letter

Enter More Information

Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 84542-11

Product Name: CUPRON ANTI-FUNGAL FIBERS AND FABRICS

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 19-May-2014

OPP Rec'd Date: 20-May-2014

Front End Date: 20-May-2014

Risk Manager Send Date: 20-May-2014

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

NOTIFICATION to add an additional alternative CSF

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Des

CSF

View/Edit

Stacy



AG-CHEM CONSULTING

PESTICIDE SCIENCE AND REGISTRATION

12208 QUINQUE LANE. CLIFTON VA 20124

(703) 266-0128 MWBROOKS@AG-CHEM.COM

(703) 266-4377 FAX

May 19, 2014

Jacqueline Hardy
Product Manager 34
Insecticide Branch
Registration Division (7505P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

**Subject: Cupron Anti-Fungal Fibers and Fabrics III
Notification to add an additional alternative CSF
EPA Reg# 84542-11**

Dear Ms. Hardy,

Ag-Chem Consulting, on behalf of Cupron Inc, hereby submits the following notification to add an additional alternative CSF for the above product. We are adding an additional registered source of active ingredient. The source is registered for the same uses as the Basic CSF.

We have enclosed two (2) copies of the proposed CSFs for your review.

Should you have any questions or require additional information, please do not hesitate to contact me at 703-266-0128.

Very Sincerely,

Dr. Matthew Brooks
Director, Ag-Chem Consulting
An Authorized Representative for Cupron Inc.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Cupron Inc. /84542-11	2. EPA Product Manager Hardy	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Cupron Inc. /Cupron Anti-Fungal Fibers and Fabrics III	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Cupron Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification to add an additional alternative CSF

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40CFR152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) _____ None
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 2 lb.	5. Location of Label Directions <input checked="" type="checkbox"/> On garment hangtag
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other affixed with plastic cord

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Dr. Matthew Brooks	Title Regulatory Consultant	Telephone No. (Include Area Code) 703-266-0128
----------------------------	--------------------------------	---

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature 	3. Title Regulatory Consultant
4. Typed Name Dr. Matthew Brooks	5. Date 5/19/14



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 15 2014

Dr. Matthew Brooks
Cupron Technologies
c/o Ag-Chem Consulting
12208 Qunique Lane
Clifton, VA 20124

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: **Cupron Anti-Fungal Fibers and Fabrics III**
EPA Registration Number: 84542-11
Application Date: February 19, 2014
Receipt Date: February 20, 2014

Dear Dr. Brooks:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide (FIFRA), as amended, is acceptable.

Proposed Amendment

- Split current label into two sublabels and adding Jock itch Claim

Label Deficiencies

A stamped label is enclosed for your records. This labeling supersedes all previous labeling. The next printing of this product must use this labeling unless subsequent changes have been approved. You must submit one copy of the final printed label before selling or distributing the product bearing the revised labeling. In accordance with 40 CFR 152.130©, you must distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling, or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and it's implementing regulations at 40 CFR 152.3.

General Comments

If you have further questions concerning this letter, then please contact me by telephone at (703) 308-6416 or by e-mail at hardy.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 308-6440 or by email at grigsby.stacey@epa.gov. When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

Sincerely,

Stacey Grigsby
6/1 Jacqueline Hardy
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Master Label containing

Sublabel 1. Athlete's Foot Label

Sublabel 2. Jock Itch Label

[Sublabel 1: Athlete's Foot Label]

CUPRON ANTI-FUNGAL FIBERS AND FABRICS III

[Additional Brand Name: Cupron AntiFungal Fibers]

Active Ingredient

Copper (I) oxide 1.95 %

Other Ingredients (Garment) 98.05 %

Total 100.00 %

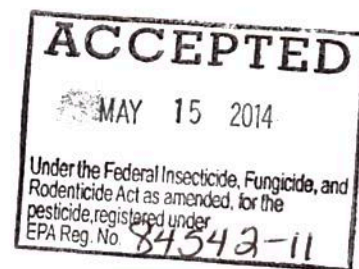
EPA Registration No. 84542- 11

EPA Establishment No *****

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by*****

Net Contents*****



Cupron Anti Fungal Fibers and Fabrics III

Master Label

4/8/2014

Page 1

Cupron Anti Fungal Fibers and Fabrics III

[When Additional Brand Name is used the statement Cupron enhanced fibers/fabric shown below is replaced with Cupron AntiFungal Fibers]

-THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Laboratory testing has shown that when cleaned regularly:

Cupron enhanced fibers/fabric will assist in reducing the spread of *T. mentagrophytes* (athlete's foot fungus).

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (athlete's foot fungus) after 12 hours of contact with [sock, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (athlete's foot fungus) on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the growth of athlete's foot fungus on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric reduce(s) the spread of *T. mentagrophytes*, athlete's foot fungus, on the surface of the sock.

Cupron enhanced fibers/fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the sock.

Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the [sock, bathmat, shoe inserts].

Cupron enhanced fibers/fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, fungus that causes athlete's foot on the sock.

THIS PRODUCT IS EFFICACIOUS UP TO 20 MACHINE WASHINGS

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

Cupron Anti Fungal Fibers and Fabrics III

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular (not compatible with silvercare machines)

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.


[Cupron Anti Fungal Fibers and Fabrics III may be used in public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE SOCKS, FOOTWEAR, SHOE INSERTS AND BATHMATS.

STORAGE AND DISPOSAL

Disposal: Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

Hang Tag Label:



Cupron AntiFungal Fibers

Cupron Antifungal Fibers Kill 99.9% of T. mentagrophytes (athlete's foot fungus) after 12 hours of contact with socks.

Active Ingredient	
Copper (I) Oxide	1.95%
Other Ingredients (Garment)	98.05%
Total	100%

EPA Registration No 84542-11 EPA Establishment No 3541-TN-001, 3541-AL-001

Manufactured for
Cupron Inc
Suite 123, 800 East Leigh Street, Richmond, VA 23219

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular
Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)
Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes
May use Clorox or similar bleach
Do not use fabric softener, or laundry detergent containing fabric softeners
Do not dry clean.

Storage and Disposal

Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.

Master Label containing

Sublabel 1. Athlete's Foot Label

Sublabel 2. Jock Itch Label

[Sublabel 2: Jock Itch Label]

CUPRON ANTI-FUNGAL FIBERS AND FABRICS III

[Additional Brand Name: Cupron AntiFungal Fibers]

Active Ingredient

Copper (I) oxide 1.95%

Other Ingredients (Garment) 98.05%

Total: 100.00%

EPA Registration No. 84542- 11

EPA Establishment No *****

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by*****

Net Contents*****

Cupron AntiFungal Fibers and Fabrics III

-THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Laboratory testing has shown that when cleaned regularly:

- Cupron enhanced fibers / fabric will assist in reducing the spread of *T. mentagrophytes* (jock itch fungus)
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (jock itch fungus) after 12 hours of contact with the [USE SITE]
- Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on [USE SITE]
- Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of jock itch on [USE SITE]
- Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of jock itch on [USE SITE]
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (jock itch fungus) on the [USE SITE]
- Cupron enhanced fibers / fabric will inhibit the growth of *T. mentagrophytes*, jock itch fungus, on [USE SITE]
- Cupron enhanced fibers / fabric reduce(s) the spread of *T. mentagrophytes*, jock itch fungus, on the surface of the [USE SITE]
- Cupron enhanced fibers / fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, jock itch fungus, on the [USE SITE]
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, jock itch fungus, on the [USE SITE]
- Cupron enhanced fibers / fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, the fungus that causes jock itch on the [USE SITE]

THIS PRODUCT IS EFFICACIOUS UP TO 20 MACHINE WASHINGS

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular (not compatible with silvercare machines)

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

[Cupron Anti Fungal Fibers and Fabrics III may be used in various public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE:-underwear, studio apparel (pants, capris, shorts, leggings, tights), yoga apparel (pants, capris, shorts, leggings, tights), run apparel (pants, capris, shorts, leggings, tights), training apparel (pants, capris, shorts, leggings, tights), team sports apparel (pants, capris, shorts, leggings, tights), team sports uniforms (pants, capris, shorts, leggings, tights), baselayer (pants, capris, shorts, leggings, tights), compression products (pants, capris, shorts, leggings, tights), warmth layers (pants, capris, shorts, leggings, tights), leg sleeves.

STORAGE AND DISPOSAL

Disposal: Discard in trash when fibers/fabric are worn out after 20 washings. Do not reuse clothing for other purposes than as sold.

Hang Tag Label:



Cupron AntiFungal Fibers

Cupron Antifungal Fibers Kill 99.9% of *T. mentagrophytes* (jock itch fungus) after 12 hours of contact with (insert site).

Active Ingredient

Copper (I) Oxide	1.95%
Other Ingredients (Garment)	98.05%
Total	100%

EPA Registration No 84542-11

EPA Establishment No 3541-TN-001, 3541-AL-001

Manufactured for
Cupron Inc
Suite 123, 800 East Leigh Street, Richmond, VA 23219

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

Storage and Disposal

Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.

Material Sent for Data Extraction

Reg # 84542-11

Description: 302

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: unAcceptable use/claim

☐ Decision #: 488341

☐ Other Action/Comments: _____

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Stacey GRIGSBY

Phone: 305.6440 Division: AD

Date: 4/4/14



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 4 2014

Dr. Matthew Brooks
Cupron Technologies
c/o Ag-Chem Consulting
12208 Qunique Lane
Clifton, VA 20124

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: **Cupron Anti-Fungal Fibers and Fabrics III**
EPA Registration Number: 84542-11
Application Date: February 19, 2014
Receipt Date: February 20, 2014

Dear Dr. Brooks:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide (FIFRA), as amended, is acceptable.

Proposed Amendment

- Split current label into two sublabels and adding Jock itch Claim

Label Deficiencies

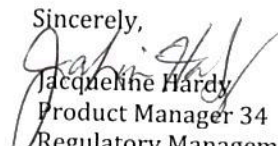
The following statement found on pages 3 and 7 are not approved " maybe used in hospitals, other healthcare facilities and various public, commercial buildings for the uses listed below". This product is not acceptable for use in hospitals or health care facilities because it does not have acceptable efficacy test data against the microorganisms required for this use/claim.

General Comments

If you would like to add these uses to the product label, please submit appropriate efficacy data to support these claims.

If you have further questions concerning this letter, then please contact me by telephone at (703) 308-6416 or by e-mail at hardy.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 308-6440 or by email at grigsby.stacey@epa.gov . When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

Sincerely,


Jacqueline Hardy
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branches

ORIGINATOR/PRODUCT REVIEWER: Stacey Grigsby						RMB II TEAM ____34____	
Decision No: 488341			Submission No: 948269			EPA File Symbol/Reg No. 84542-11	
PRIA Fee: \$ _____			Action Code: 302				
GPRA:	FQPA		Non-FQPA			Product Re-reg.	
PRIA:	ME-TOO	New Use <input type="checkbox"/>		Old Chemical		New Chemical <input type="checkbox"/>	Amend w/data
		MONTH	DAY		YEAR		
APPLICATION DATE		2	19		2014		
EPA PIN DATE		2	20		2014		
DATE PM RECEIVED FROM FRONT END					2014		
DATE SENT TO SCIENCE					2014		
DATE RECEIVED FROM SCIENCE							
NEGOTIATED DUE DATE					DATE DUE OUT OF AGENCY	4/4/14	
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure/Residue

Comments: Please provide hard and electronic copy of deliverable(s).

Label Amendment: Please review the label. Registrant created two sublabels by splitting the Athlete's Foot Fungus claims from the Jock Itch claims.

Note: Validate w/ efficacy that the statement "maybe used in hospitals, other healthcare facilities, and various public, commercial buildings for the uses listed below" is acceptable. Its on page 3 and 7

S: 948269

Milestone Label:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Company: 84542 CUPRON INC.



Billable: ☐ Yes ☒ No

Print Letter

Enter More Information

Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 84542-11

Product Name: CUPRON ANTI-FUNGAL FIBERS AND FABRICS

Override#:

Me Too

Section3:

Me Too Product

Name:

Application Date: 19-Feb-2014



OPP Rec'd Date: 20-Feb-2014



Front End Date: 27-Feb-2014



Risk Manager Send Date: 28-Feb-2014



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Amendment to split current label into two sub-labels

Form A: ☐

Signature Date:

Form B: ☐

New Ingredient

Request Date:

New Ingredient

Received Date:

Signature Date:

Receipt Content

Study

Paper Label

View/Edit

due date
3/21/14



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 28, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MATTHEW BROOKS, PH.D.
AG-CHEM CONSULTING
CUPRON INC.
12208 QUINQUE LANE
CLIFTON, VA 20124-

PRODUCT NAME: CUPRON ANTI-FUNGAL FIBERS AND FABRICS III
COMPANY NAME: CUPRON INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 84542-11
EPA RECEIPT DATE: 02/20/14

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 34, at {703-305-4616}.

Sincerely,

A handwritten signature in black ink, appearing to be "J. E. [unclear]".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



Fee for Service

{948269Y~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☒ AD
- ☐ BPPD
- ☐ RD

Risk Mgr.

34

Receipt No.

S-

948269

EPA File Symbol/Reg. No.

84542-11

Pin-Punch Date:

2/20/2014



This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ ____

Parent/Child Decisions:



Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer:

Team 1

Date:

2-28-14

Remarks:



United States
Environmental Protection Agency
Washington, DC 20460

Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Cupron Inc./84542-11	2. EPA Product Manager Jacqueline Hardy	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Cupron Inc. /Cupron Anti-Fungal Fibers and Fabrics III	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Cupron Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to split current label into two sublabels and add Jock Itch claims

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) _____ None	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2 lb.		5. Location of Label Directions <input checked="" type="checkbox"/> On garment hangtag	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other affixed with plastic cord			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Dr. Matthew Brooks	Title Regulatory Consultant	Telephone No. (Include Area Code) 703-266-0128
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant	
4. Typed Name Dr. Matthew Brooks	5. Date February 19, 2014	



Ag-Chem Consulting
Pesticide Science and Registration
12208 Quinque Lane, Clifton VA 20124
(703) 266-0128 mwbrooks01@yahoo.com
(703) 266-4377 Fax

February 17, 2014

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington VA 22202

Attn: Mark Suarez
Product Manager 13

**Re: Registration of LambdaStar Urban Cap
EPA File Symbol 71532-GG**

Dear Mr. Suarez;

On behalf of LG Life Science Ltd., Ag-Chem Consulting LLC is hereby submitting the following Product Chemistry data, formatted in accordance with Pesticide Registration notice 86-5, in support of reregistration for the above product.

Guideline	MRID	Study Title
OPPTS 830.6317, and 830.6320		LambdaStar 9.7 CS: Accelerated Storage Stability and Corrosion Characteristics Study #377742

Please note, although the study is named LambdaStar 9.7CS, it is a modified formulation of that product and has been submitted as a new product called LambdaStar Urban Cap.

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of LG Life Science Ltd.



AG-CHEM CONSULTING

PESTICIDE SCIENCE AND REGISTRATION

12208 QUINQUE LANE, CLIFTON VA 20124

(703) 266-0128 MWBROOKS@AG-CHEM.COM

(703) 266-4377 FAX

February 19, 2014

Jacqueline Hardy
Product Manager 34
Insecticide Branch
Antimicrobials Division (7510P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Cupron AntiFungal Fibers and Fabrics III
Amendment to split current label into two sublabels and add Jock
Itch claims
EPA Reg. No. 84542-11

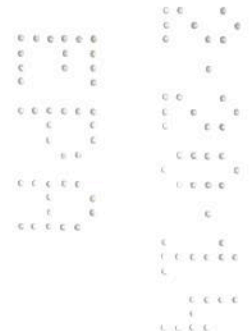
Dear Ms. Hardy,

Ag-Chem Consulting, on behalf of Cupron, Inc., hereby submits the following amendment to split the current label of the above product into two sublabels, one to treat Athlete's Foot and one to treat Jock Itch. We have also revised the hang tag label to accurately reflect the commercial hang tag. These changes are identical to the ones just approved for Cupron AntiFungal Fibers and Fabrics II (EPA # 84542-10).

Should you have any questions or require additional information, please do not hesitate to contact me at 703-266-0128.

Very Sincerely,

Dr. Matthew Brooks
Director, Ag-Chem Consulting
An Authorized Representative for Cupron Inc



Master Label containing

Sublabel 1. Athlete's Foot Label

Sublabel 2. Jock Itch Label

[Sublabel 1: Athlete's Foot Label]

CUPRON ANTI-FUNGAL FIBERS AND FABRICS III

[Additional Brand Name: Cupron AntiFungal Fibers]

Active Ingredient

Copper (I) oxide 1.95 %

Other Ingredients (Garment) 98.05 %

Total 100.00 %

EPA Registration No. 84542- 11

EPA Establishment No *****

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by*****

Net Contents*****

Cupron Anti Fungal Fibers and Fabrics III

[When Additional Brand Name is used the statement Cupron enhanced fibers/fabric shown below is replaced with Cupron AntiFungal Fibers]

-THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Laboratory testing has shown that when cleaned regularly:

Cupron enhanced fibers/fabric will assist in reducing the spread of *T. mentagrophytes* (athlete's foot fungus).

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (athlete's foot fungus) after 12 hours of contact with [sock, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of athlete's foot on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (athlete's foot fungus) on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers / fabric will inhibit the growth of athlete's foot fungus on the [socks, bathmats, shoe inserts].

Cupron enhanced fibers/fabric reduce(s) the spread of *T. mentagrophytes*, athlete's foot fungus, on the surface of the sock.

Cupron enhanced fibers/fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, athlete's foot fungus, on the sock.

Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* athlete's foot fungus, on the [sock, bathmat, shoe inserts].

Cupron enhanced fibers/fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, fungus that causes athlete's foot on the sock.

THIS PRODUCT IS EFFICACIOUS UP TO 20 MACHINE WASHINGS

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

Cupron Anti Fungal Fibers and Fabrics III

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular (not compatible with silvercare machines)

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

[Cupron Anti Fungal Fibers and Fabrics III may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE SOCKS, FOOTWEAR, SHOE INSERTS AND BATHMATS.

STORAGE AND DISPOSAL

Disposal: Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

Hang Tag Label:



Cupron AntiFungal Fibers

Cupron Antifungal Fibers Kill 99.9% of T. mentagrophytes (athlete's foot fungus) after 12 hours of contact with socks.

Active Ingredient

Copper (I) Oxide	1.95%
Other Ingredients (Garment)	98.05%
Total	100%

EPA Registration No 84542-11

EPA Establishment No 3541-TN-001, 3541-AL-001

Manufactured for
Cupron Inc
Suite 123, 800 East Leigh Street, Richmond, VA 23219

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

Storage and Disposal

Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.

Master Label containing

Sublabel 1. Athlete's Foot Label

Sublabel 2. Jock Itch Label

[Sublabel 2: Jock Itch Label]

CUPRON ANTI-FUNGAL FIBERS AND FABRICS III

[Additional Brand Name: Cupron AntiFungal Fibers]

Active Ingredient

Copper (I) oxide

~~2.95%~~ 1.95%

Other Ingredients (Garment)

98.05%

Total:

100.00%

EPA Registration No. 84542- 11

EPA Establishment No *****

Made in the United States by Cupron Inc, Richmond, VA 23219

Distributed by*****

Net Contents*****

Cupron Anti Fungal Fibers and Fabrics III

Master Label

2/19/2014

Page 5

Cupron AntiFungal Fibers and Fabrics III

-THIS TEXTILE (OR IDENTIFIED ACTIVE AREA) CONTAINS CUPRON ANTI-MICROBIAL TECHNOLOGY

Laboratory testing has shown that when cleaned regularly:

- Cupron enhanced fibers / fabric will assist in reducing the spread of *T. mentagrophytes* (jock itch fungus)
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes* (jock itch fungus) after 12 hours of contact with the [USE SITE]
- Cupron enhanced fibers / fabric will inhibit the propagation and harboring of *T. mentagrophytes* on [USE SITE]
- Cupron enhanced fibers / fabric will help to inhibit the growth of *T. mentagrophytes* the causative agent of jock itch on [USE SITE]
- Cupron enhanced fibers / fabric will help to suppress the growth of *T. mentagrophytes* the fungus that is the causative agent of jock itch on [USE SITE]
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of the *T. mentagrophytes* (jock itch fungus) on the [USE SITE]
- Cupron enhanced fibers / fabric will inhibit the growth of *T. mentagrophytes*, jock itch fungus, on [USE SITE]
- Cupron enhanced fibers / fabric reduce(s) the spread of *T. mentagrophytes*, jock itch fungus, on the surface of the [USE SITE]
- Cupron enhanced fibers / fabric prevent(s) the growth of 99.9% of *T. mentagrophytes*, jock itch fungus, on the [USE SITE]
- Cupron enhanced fibers / fabric will [reduce, inhibit, suppress, kill] 99.9% of *T. mentagrophytes*, jock itch fungus, on the [USE SITE]
- Cupron enhanced fibers / fabric significantly reduce(s) 99.9% of *T. mentagrophytes*, the fungus that causes jock itch on the [USE SITE]

THIS PRODUCT IS EFFICACIOUS UP TO 20 MACHINE WASHINGS

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular (not compatible with silvercare machines)

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

[Cupron Anti Fungal Fibers and Fabrics III may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the uses listed below.]

TEXTILES ARE TO BE USED TO MAKE:-underwear, studio apparel (pants, capris, shorts, leggings, tights), yoga apparel (pants, capris, shorts, leggings, tights), run apparel (pants, capris, shorts, leggings, tights), training apparel (pants, capris, shorts, leggings, tights), team sports apparel (pants, capris, shorts, leggings, tights), team sports uniforms (pants, capris, shorts, leggings, tights), baselayer (pants, capris, shorts, leggings, tights), compression products (pants, capris, shorts, leggings, tights), warmth layers (pants, capris, shorts, leggings, tights), leg sleeves.

STORAGE AND DISPOSAL

Disposal: Discard in trash when fibers/fabric are worn out after 20 washings. Do not re-use clothing for other purposes than as sold.

Hang Tag Label:



Cupron AntiFungal Fibers

Cupron Antifungal Fibers Kill 99.9% of *T. mentagrophytes* (jock itch fungus) after 12 hours of contact with (insert site).

Active Ingredient

Copper (I) Oxide	1.95%
Other Ingredients (Garment)	98.05%
Total	100%

EPA Registration No 84542-11

EPA Establishment No 3541-TN-001, 3541-AL-001

Manufactured for
Cupron Inc
Suite 123, 800 East Leigh Street, Richmond, VA 23219

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product will retain its antimicrobial properties for 20 washings if maintained in the following manner:

Machine Wash Regular

Temperature Cold, Warm, or Hot (up to 176 degrees Fahrenheit)

Tumble dry hot (up to 347 degrees Fahrenheit) for up to 30 minutes

May use Clorox or similar bleach

Do not use fabric softener, or laundry detergent containing fabric softeners

Do not dry clean.

Storage and Disposal

Discard in trash when fibers/fabric are worn out or after 20 washings. Do not reuse clothing for other purposes than as sold.

The use of this textile is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and sanitizing/disinfection of textiles. This textile has been shown to reduce microbial contamination, but it does not prevent cross contamination.



AG-CHEM CONSULTING

PESTICIDE SCIENCE AND REGISTRATION

12208 QUINQUE LANE, CLIFTON VA 20124

(703) 266-0128 MWBROOKS@AG-CHEM.COM

(703) 266-4377 FAX

July 26, 2013

Jacqueline Campbell
Product Manager 34
Insecticide Branch
Registration Division (7505P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

**Subject: Cupron Anti-Fungal Fibers and Fabrics III
Amendment to Add Alternate CSF
EPA Reg# 84542-11**

Dear Ms. Campbell,

Ag-Chem Consulting, on behalf of Cupron Inc, hereby submits the following amendment to add an alternate CSF for the above product. We have revised the concentration of [REDACTED] We have balanced this by deleting the [REDACTED]

We have enclosed two (2) copies of the proposed CSFs for your review.

Should you have any questions or require additional information, please do not hesitate to contact me at 703-266-0128.

Very Sincerely,

Dr. Matthew Brooks
Director, Ag-Chem Consulting
An Authorized Representative for Cupron Inc.

Inert ingredient information may be entitled to confidential treatment

Material Sent for Data Extraction

Reg # 84542-11

Description: Amend.

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☒ Other: _____

☒ Decision #: 482370

☐ Other Action/Comments: _____

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: J. Rivers

Phone: _____ Division: AD

Date: 12/13/13

Created February 3, 2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 11 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: Formulation Amendment to Add Alternate CSFs for EPA Registrations 84542-10 and 84542-11

Dear Dr. Brooks:

The amendments referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is not acceptable.

Changes in the product formulation are significant enough such that confirmatory efficacy testing must be addressed.

Background

For new products, confirmatory efficacy data are required for formulations that an applicant manufactures that duplicate a product already registered with complete supporting efficacy data. In such cases, the chemical composition, manufacturing procedure, label claims, and directions for use must be identical in substance to those of the original registration, and specific references (Master Record ID Numbers [MRID]) to the supporting data developed for the original product must be cited by the applicant.

Confirmatory efficacy data are also required for minor formulation changes in an already registered product. In these situations, the change in the formulation is relatively minor, e.g., a change of an inert ingredient.

For minor formulation changes, confirmatory efficacy data are *not* required when a different fragrance is substituted for a fragrance already present in a formulation, or when a different dye is substituted for a dye already present in a formulation. The new fragrance or dye must also be added at the same nominal concentration with the same certified limits as the replaced fragrance or dye to be exempt from confirmatory testing. Additionally, products that are aerosol formulations require confirmatory efficacy data to be submitted for all formulation changes, except the addition or substitution of fragrances. Fragrances for antimicrobial aerosol products making public health claims can be added by notification provided the new fragrance(s) is within the certified limits established for fragrances already approved for the product.

For minor formulation changes, any changes to a product's inert ingredients or their certified limits, other than the circumstances with fragrances and dyes mentioned above, will require

confirmatory efficacy data unless sufficient rationale is presented and accepted by the Agency. Such applications would fall under PRIA and be assigned a PRIA code of A570, have a four (4) month review timeframe, and be assessed a fee of \$3,474. Refer to the relevant OCSPP 810 series guideline for specific details on confirmatory testing. Every pest microorganism claimed on the label must be tested, with the exception of viruses. Confirmatory efficacy data for viruses may use the hierarchy approach with the hardest to kill virus listed on the label being tested. In addition, products that include *C. difficile* or *Mycobacterium* claims are required to perform full efficacy testing data to support these organisms.

For minor formulation changes, if the agency determines that already submitted/cited product chemistry and/or acute toxicity data cannot be bridged to support the proposed alternate formulation, then that formulation will not be allowed under the existing registration. Central to this determination is a consideration as to whether the product labeling accurately reflects the alternate formulation with respect to its chemical properties and acute toxicity profile. Per 40 CFR Part 152.43,


- 1) The alternate formulation must have the same certified limits for each active ingredient as the basic formulation.*
- (2) If the alternate formulation contains an inert ingredient or impurity of toxicological significance, the formulation must have the same upper certified limit for that substance as the basic formulation;*
- (3) The label text of the alternate formulation product must be identical to that of the basic formulation.*
- (4) The analytical method required under § 158.355 of this chapter must be suitable for use on both the basic formulation and the alternate formulation.*

Confirmatory efficacy studies should be conducted under Good Laboratory Practices (GLP). If not, they should be accompanied with rationale as to why the study, or portions of it, did not comply with GLP to aid the reviewer in determining the impact of non-GLP conductance on study acceptability.

In addition to the confirmatory efficacy data, a new manufacturing process will need to be provided for each alternate formulation.

If you have further questions concerning this letter, please contact me at (703) 308-6416 or Campbell.jacqueline@epa.gov or Stacey Grigsby at (703) 305-6440 or grigsby.stacey@epa.gov.

Sincerely,



Jacqueline Hardy
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branches

ORIGINATOR/PRODUCT REVIEWER: <u>Lorena Rivas</u>						RMB II TEAM <u>34</u>	
Decision No: <u>482370</u>			Submission No: <u>938815</u>			EPA File Symbol/Reg No. <u>84542-11</u>	
PRIA Fee: \$ _____			Action Code: <u>362</u>				
GPRA:	FQPA		Non-FQPA			Product Re-reg.	
PRIA:	ME-TOO	New Use <input type="checkbox"/>	Old Chemical		New Chemical <input type="checkbox"/>	Amend w/data	
		MONTH	DAY		YEAR		
APPLICATION DATE		<u>7</u>	<u>26</u>		2013		
EPA PIN DATE		<u>7</u>	<u>29</u>		2013		
DATE PM RECEIVED FROM FRONT END					2013		
DATE SENT TO SCIENCE					2013		
DATE RECEIVED FROM SCIENCE							
NEGOTIATED DUE DATE					DATE DUE OUT OF AGENCY		
Type of Data:	PSB Product Chemistry <u>X</u>	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure/Residue

Comments: Please provide hard and electronic copy of deliverable(s).

Minor Formulation Change

Product Chemistry: Pls review alternate formulation

changing fiber concentration



Inert ingredient information may be entitled to confidential treatment



AG-CHEM CONSULTING

PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS@AG-CHEM.COM
(703) 266-4377 FAX

July 26, 2013

Jacqueline Campbell
Product Manager 34
Insecticide Branch
Registration Division (7505P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

**Subject: Cupron Anti-Fungal Fibers and Fabrics III
Amendment to Add Alternate CSF
EPA Reg# 84542-11**

Dear Ms. Campbell,

Ag-Chem Consulting, on behalf of Cupron Inc, hereby submits the following amendment to add an alternate CSF for the above product. We have revised the concentration of [REDACTED] We have balanced this by deleting the [REDACTED]

We have enclosed two (2) copies of the proposed CSFs for your review.

Should you have any questions or require additional information, please do not hesitate to contact me at 703-266-0128.

Very Sincerely,

Dr. Matthew Brooks
Director, Ag-Chem Consulting
An Authorized Representative for Cupron Inc.

Inert ingredient information may be entitled to confidential treatment



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Cupron Inc. /84542-11	2. EPA Product Manager Campbell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Cupron Inc. /Cupron Anti-Fungal Fibers and Fabrics III	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Cupron Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to add alternative CSF

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) _____	None
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2 lb.		5. Location of Label Directions <input checked="" type="checkbox"/> On garment hangtag	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other affixed with plastic cord			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
Name Dr. Matthew Brooks		Title Regulatory Consultant		Telephone No. (include Area Code) 703-266-0126
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.				5. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant		
4. Typed Name Dr. Matthew Brooks		5. Date 7/26/13		

DATA PACKAGE BEAN SHEET

Date: 28-Aug-2013

Page 1 of 1

Decision #: 482370

DP #: (414461)

NON PRIA

Parent DP #:

Submission #: 938815

E-Sub #:

*** Registration Information ***

Registration: 84542-11 - CUPRON ANTI-FUNGAL FIBERS AND FABRICS III

Company: 84542 - CUPRON INC.

Risk Manager:

Risk Manager Reviewer: Lorena Rivas LRIVAS

Sent Date:

PRIA Due Date: 27-Oct-2013

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (362) FORMULA CHANGE; TECHNICAL;

Ingredients: 025601, Cuprous oxide(1.95%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 28-Aug-2013

Due Back:

DP Ingredient: 025601, Cuprous oxide

DP Title: Product Chemistry

CSF Included: ☒ Yes ☐ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Team Name: CTT

Reviewer Name:

Contractor Name:

Last Possible Science Due Date: 21 Oct. 13
~~12-Sep-2013~~

Science Due Date:

Sub Data Package Due Date:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Please review the minor formulation change on the CSF changing by deleting the [REDACTED] Active ingredient: Cuprous Oxide.

They are balancing this

Inert ingredient information may be entitled to confidential treatment

Receipt for Section 3

S: 938815

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 84542 CUPRON INC.

V

Risk Manager: Antimicrobials Division, Risk Management Team 34

Product #: 84542-11 Product Name: CUPRON ANTI-FUNGAL FIBERS AND FABRIC

Override#:

Me Too

Section3:

Me Too

Product Name:

Application Date: 26-Jul-2013



OPP Rec'vd Date: 29-Jul-2013



Front End Date: 29-Jul-2013



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

CSF amendment

Form A: ☐

Signature Date:

Form B: ☐

New Ingredient

Request Date:

New Ingredient

Received Date:

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

CSF

View/Edit



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 30, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MATTHEW BROOKS, PH.D.
AG-CHEM CONSULTING
CUPRON INC.
12208 QUINQUE LANE
CLIFTON, VA 20124-

PRODUCT NAME: CUPRON ANTI-FUNGAL FIBERS AND FABRICS III
COMPANY NAME: CUPRON INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 84542-11
EPA RECEIPT DATE: 07/29/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 34, at {703-308-6416}.

Sincerely,

A handwritten signature in black ink, appearing to be "Jeg", is written below the word "Sincerely,".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

{938815>~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: ____

for Division

- ☒ AD
- ☐ BPPD
- ☐ RD

Risk Mgr. **34**

Receipt No.

S- **938815**

EPA File Symbol/Reg. No.

84542-11

Pin-Punch Date:

7/29/2013



This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ ____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: TL

Date: JUL 29 2013

Remarks:

NEW APPLICATIONS

DATE: 9/21/12

FILE NUMBER: 84542-RR

FEP (OPPIN ENTRY) SB SEP 21 2012
(Initial & date)

FILE ROOM: _____
(Initial & date)

SIG: _____
(Initial & date)

FILE ROOM: _____
(Initial & date)

✓ ASSIGN TO PM 34 (NO DATA)

____ JACKET TO SHELF (DATA)